Supporting Science

Why investing in clinical research makes good marketing sense

by Chris Baker

Sometimes safeguards are put in place that provide benefits to all parties, and that is certainly the case when companies support research about their nutritional ingredients and/or finished products. Strong science that backs up product claims protects both consumers and marketers. Good research supporting product claims provides assurance of the product's efficacy.

This hasn't always been the case. Back in the days of the Wild West, "doctors" and other self-proclaimed healers traveled the countryside hawking potions and pills they claimed would cure any and every malady. Often they were selling nothing more than topical oils, or sugar water with a little alcohol thrown in. While their customers may have come back for more, it was often for the buzz the booze provided rather than for medicinal benefits. At best, these products were benign; often, they delivered more harm than benefit.

Today, government regulations are in place to prevent many of the most egregious false claims. While some companies are still promoting questionable products with more questionable claims, the majority of dietary supplement companies have a vested interest in making certain their products are effective. And it is the law that companies have validated research to support their marketing claims.

To provide this substantiation, many companies turn to outside research entities to provide unbiased clinical data about the products. Clinical research firms develop study protocol, including the number of subjects, timeline, primary and secondary outcomes, measuring tools and more. A study may take place over a short period of time, or it can last several weeks, depending on the nature of the product or treatment and the marketing needs of the company.

The double blind study is considered the gold standard for quality research. Such studies include two groups of subjects—one is given the active intervention, the other an inactive placebo that is indistinguishable from the test product. Neither the researchers nor the subjects are aware of whether they're taking the test product or the placebo; thus, the bias of both the patient and the doctor are removed, making the study "double blind." After the intervention phase, the researchers uncover which subjects were on which protocol so the effects can be appropriately evaluated and compared.

Pre- and Post-Design Research

Many companies are turning to outside researchers to validate claims for existing products or ones that have been formulated in R&D. It is not uncommon for companies to develop a formula based on existing research, whether the studies were performed in-house or conducted by an outside group. However, further research is often necessary to ensure the product being marketed has the effects being sought; combining ingredients can have synergistic effects in a final formula, and studies on a single ingredient are not necessarily conclusive for the effects of that ingredient in combination. FTC requires companies have scientific data from an independent source to validate the claims on their specific products.

There are various options for developing the required substantiation. Companies can work with universities or other independent public entities, supporting research on the products or treatments. However, it is important to remember universities generally publish all the research they perform, which may not support the company's goals, particularly with a proprietary formulation. This also disseminates more information regarding an ingredient or product before the optimal formulation is achieved.

Another option is working with contract research organizations (CROs). Such independent companies are experienced in working with clients to make sure they get the maximum science for the minimum cost. Also, there is not necessarily an obligation to publish the results; therefore, if the results of a clinical trial are not positive, the CRO and company have the opportunity to re-formulate and repeat the trial to ensure efficacy of the product and promote the positive information about the product to the public.

Clinical research and CROs are growing rapidly as more companies understand the need to validate product claims. Last year, biotech and pharmaceutical companies spent more than $17 billion outsourcing research and clinical trials to CROs, according to the market research firm Frost & Sullivan, a number that is projected to grow by 40 percent by 2011. Increasingly, nutraceutical and dietary supplement firms will follow in those steps, further driving the research market and ensuring consumers receive the most effective products with substantiated claims. ❑

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